IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

SANOFI and SANOFI-AVENTIS U.S. LLC Plaintiffs, v. ALKEM LABORATORIES LTD. and ASCEND LABORATORIES, LLC Defendants.	)	Civil Action No.: 14-cv-1957

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Sanofi and Sanofi-Aventis U.S. LLC ("Sanofi U.S.") (collectively, "Plaintiffs") for their Complaint against defendants Alkem Laboratories Ltd. ("Alkem") and Ascend Laboratories, LLC ("Ascend") (collectively, "Defendants") hereby allege as follows:

THE PARTIES

1. Plaintiff Sanofi is a corporation organized and existing under the laws of France, having its principal place of business at 54 rue La Boétie, 75008 Paris, France.

2. Plaintiff Sanofi U.S. is a wholly owned U.S. subsidiary of Sanofi and is a company organized and existing under the laws of the state of Delaware, having commercial headquarters at 55 Corporate Drive, Bridgewater, New Jersey 08807.

3. On information and belief, defendant Alkem is a company organized and existing under the laws of India, having a principal place of business at Alkem House, Devashish, Senapati Bapat Marg, Lower Parel (West), Mumbai 400013, Maharashtra, India.

4. On information and belief, defendant Ascend is a company organized and existing under the laws of the state of New Jersey, having a principal place of business at 180 Summit Ave. Suite 200, Montvale, NJ 07645.

5. On information and belief, Ascend is a wholly owned subsidiary of ThePharmaNetwork LLC, which is in turn a wholly owned subsidiary of defendant Alkem.

JURISDICTION AND VENUE

6. This is an action for patent infringement arising under the Patent Laws of the United States and the Food and Drug Laws of the United States, Titles 35 and 21, United States Code. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338.

7. This Court has personal jurisdiction over Alkem, among other reasons, because Alkem has consented to personal jurisdiction in this judicial district.

8. By letters dated January 31, 2014 and February 11, 2014, and pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95(c), Alkem notified Plaintiffs that it had submitted Abbreviated New Drug Application (ANDA) No. 205895 to the FDA. In its letter, Alkem certified pursuant to 21 C.F.R. § 314.95(c)(7) that Imron T. Aly, Esq., E-mail: ialy@winston.com, Winston &Strawn LLP, 35 West Wacker Dr., Chicago, IL 60601 "is authorized to accept service of process of process on behalf of Alkem in connection with its ANDA No. 205895 relating to the drug product."

9. Alkem's January 31, 2014 and February 11, 2014 letters further state that "Alkem is an Indian corporation, and consents to jurisdiction in Illinois."

10. On information and belief, Alkem is in the business of manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, including in the state of Illinois. On information and belief, Alkem directly or through its affiliates and agents (including Ascend), formulates, manufactures, packages, markets, and/or sells pharmaceutical products throughout the United States, including in this judicial district.

11. This Court has personal jurisdiction over Ascend. On information and belief, Ascend is in the business of marketing, distributing, and selling pharmaceutical products, including generic pharmaceuticals manufactured by Alkem, throughout the United States, including in the state of Illinois.

12. On information and belief, Defendants collaborate to manufacture, import, market, distribute, and/or sell pharmaceutical products (including generic drug products manufactured and sold pursuant to ANDAs) throughout the United States, including in this judicial district.

13. On information and belief, upon approval of Alkem's ANDA No. 205895, Defendants and/or their affiliates or agents will market and sell Alkem's Dronedarone Hydrochloride Tablets ("Alkem's Proposed Generic Product") in Illinois and throughout the United States and will derive substantial revenue therefrom. On information and belief, upon Approval of Alkem's ANDA, Defendants will sell Alkem's Proposed Generic Product in the state of Illinois and Ascend will be involved in the sale, marketing, and/or distribution of the product.

14. On information and belief, upon approval of Alkem's ANDA, Alkem, Ascend, and/or their affiliates or agents will place Alkem's Proposed Generic Product into the stream of commerce with the reasonable expectation or knowledge and the intent that such product will ultimately be purchased and used by consumers in this judicial district.

15. This Court has personal jurisdiction over Defendants by virtue of, *inter alia*, the above-mentioned facts.

16. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391 and 28 U.S.C. § 1400(b).

THE PATENTS-IN-SUIT

17. Sanofi U.S. holds approved New Drug Application ("NDA") No. 022425 for dronedarone tablets, 400 mg, which are prescribed and sold in the United States under the trademark Multaq®. The U.S. Food and Drug Administration ("FDA") approved NDA No. 022425 on July 1, 2009. Multaq® tablets are indicated to reduce the risk of hospitalization for atrial fibrillation in patients in sinus rhythm with a history of paroxysmal or persistent atrial fibrillation.

18. United States Patent No. 7,323,493 ("the '493 patent," copy attached as Exhibit A) is entitled "Solid Pharmaceutical Composition Containing Benzofuran Derivatives" and was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on January 29, 2008. The '493 patent claims, *inter alia,* pharmaceutical compositions containing dronedarone. The '493 patent is listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Multaq® tablets (NDA No. 022425).

19. The named inventors on the '493 patent are Bernard Abramovici, Jean-Claude Gautier, Jean-Claude Gromenil, and Jean-Marie Marrier. The '493 patent is assigned to Sanofi.

20. United States Patent No. 8,318,800 ("the '800 patent," copy attached as Exhibit B) is entitled "Solid Pharmaceutical Compositions Containing Benzofuran Derivatives" and was duly and legally issued by the USPTO on November 27, 2012. The '800 patent claims, *inter alia*, pharmaceutical compositions containing dronedarone. The '800 patent issued from a continuation of the application that issued as the '493 patent. The '800 patent is listed in the Orange Book for Multaq® tablets (NDA No. 022425).

21. The named inventors on the ’800 patent are Bernard Abramovici, Jean-Claude Gautier, Jean-Claude Gromenil, and Jean-Marie Marrier. The ’800 patent is assigned to Sanofi.

22. United States Patent No. 8,410,167 (“the ’167 patent,” copy attached as Exhibit C) is entitled “Use of Dronedarone for the Preparation of a Medicament for Use in the Prevention of Cardiovascular Hospitalization or of Mortality” and was duly and legally issued by the USPTO on April 2, 2013. The ’167 patent claims, *inter alia*, methods of decreasing the risk of cardiovascular hospitalization in certain patients by administering dronedarone. The ’167 patent is listed in the Orange Book for Multaq® tablets (NDA No. 022425).

23. The named inventors on the ’167 patent are Davide Radzik, Martin Van Eickels, Nacéra Hamdani, and Christophe Gaudin. The ’167 patent is assigned to plaintiff Sanofi.

24. United States Patent No. 8,602,215 (“the ’215 patent,” copy attached as Exhibit D) is entitled “Methods for Reducing the Risk of an Adverse Dronedarone/Beta-Blockers Interaction in a Patient Suffering from Atrial Fibrillation” and was duly and legally issued by the USPTO on December 10, 2013. The ’215 patent claims, *inter alia*, methods for managing the risk of dronedarone/beta-blocker interaction in patients with paroxysmal or persistent atrial fibrillation or atrial flutter. The ’215 patent is listed in the Orange Book for Multaq® tablets (NDA No. 022425).

25. The named inventor on the ’215 patent is Davide Radzik. The ’215 patent is assigned to Sanofi.

CLAIMS FOR RELIEF – PATENT INFRINGEMENT

26. Alkem submitted ANDA No. 205895 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Dronedarone Hydrochloride Tablets ("Alkem's Proposed Generic Product").

27. On information and belief, ANDA No. 205895 seeks FDA approval of Alkem's Proposed Generic Product for the indication of reducing the risk of hospitalization for atrial fibrillation in patients in sinus rhythm with a history of paroxysmal or persistent atrial fibrillation.

28. On information and belief, Ascend actively participated in and/or directed activities related to the submission of ANDA No. 205895 and the development of Alkem's Proposed Generic Product, was actively involved in preparing the ANDA, and/or intends to directly benefit from and has a financial stake in the approval of the ANDA. On information and belief, upon approval of Alkem's ANDA, Ascend will be involved in the manufacture, distribution, and/or marketing of Alkem's Proposed Generic Product.

29. By letter dated January 31, 2014, and pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95(c), Alkem notified Plaintiffs that it had submitted ANDA No. 205895 to the FDA seeking approval to engage in the commercial manufacture, use, sale, and/or importation of Alkem's Proposed Generic Product before the expiration of the '493 patent, the '800 patent, and the '167 patent.

30. In its January 31, 2014 letter, Alkem notified Plaintiffs that, as a part of its ANDA, it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV Certification") with respect to the '493 patent, the '800 patent, and the '167 patent. On information and belief, Alkem certified that, in its opinion and to the best of its

knowledge, the ’493 patent, the ’800 patent, and the ’167 patent are invalid and/or will not be infringed by the manufacture, use, or sale of Alkem’s Proposed Generic Product.

31. By letter dated February 11, 2014, and pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95(c), Alkem further notified Plaintiffs that it had submitted ANDA No. 205895 to the FDA seeking approval to engage in the commercial manufacture, use, sale, and/or importation of Alkem’s Proposed Generic Product before the expiration of the ’215 patent.

32. In its February 11, 2014 letter, Alkem notified Plaintiffs that, as a part of its ANDA, it had also filed a Paragraph IV Certification with respect to the ’215 patent. On information and belief, Alkem certified that, in its opinion and to the best of its knowledge, the ’215 patent is invalid and/or will not be infringed by the manufacture, use, or sale of Alkem’s Proposed Generic Product.

COUNT I

Infringement of U.S. Patent No. 7,323,493 Under 35 U.S.C. §271(e)(2)

33. Plaintiffs repeat and reallege paragraphs 1 through 32 as if fully set forth herein.

34. By submitting ANDA No. 205895 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Alkem’s Proposed Generic Product throughout the United States prior to the expiration of the ’493 patent, Defendants committed an act of infringement of the ’493 patent under 35 U.S.C. §271(e)(2). On information and belief, Defendants were aware of the ’493 patent at the time the ANDA was submitted.

35. The commercial manufacture, use, offer for sale, sale, and/or importation of Alkem's Proposed Generic Product, for which Alkem seeks approval in ANDA No. 205895, will infringe, induce infringement, and/or contributorily infringe one or more claims of the '493 patent under 35 U.S.C. §§ 271(a), 271(b), and/or 271(c).

36. Plaintiffs will be irreparably harmed by Defendants' infringing activities and do not have an adequate remedy at law

COUNT II

Infringement of U.S. Patent No. 8,318,800 Under 35 U.S.C. §271(e)(2)

37. Plaintiffs repeat and reallege paragraphs 1 through 36 as if fully set forth herein.

38. By submitting ANDA No. 205895 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Alkem's Proposed Generic Product throughout the United States prior to the expiration of the '800 patent, Defendants committed an act of infringement of the '800 patent under 35 U.S.C. §271(e)(2). On information and belief, Defendants were aware of the '800 patent at the time the ANDA was submitted.

39. The commercial manufacture, use, offer for sale, sale, and/or importation of Alkem's Proposed Generic Product, for which Alkem seeks approval in ANDA No. 205895, will infringe, induce infringement, and/or contributorily infringe one or more claims of the '800 patent under 35 U.S.C. §§ 271(a), 271(b), and/or 271(c).

40. Plaintiffs will be irreparably harmed by Defendants' infringing activities and do not have an adequate remedy at law.

COUNT III

Infringement of U.S. Patent No. 8,410,167 Under 35 U.S.C. §271(e)(2)

41. Plaintiffs repeat and reallege paragraphs 1 through 40 as if fully set forth herein.

42. By submitting ANDA No. 205895 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Alkem's Proposed Generic Product throughout the United States prior to the expiration of the '167 patent, Defendants committed an act of infringement of the '167 patent under 35 U.S.C. §271(e)(2). On information and belief, Defendants were aware of the '167 patent at the time the ANDA was submitted.

43. The commercial manufacture, use, offer for sale, sale, and/or importation of Alkem's Proposed Generic Product, for which Alkem seeks approval in ANDA No. 205895, will infringe, induce infringement, and/or contributorily infringe one or more claims of the '167 patent under 35 U.S.C. §§ 271(a), 271(b), and/or 271(c).

44. Plaintiffs will be irreparably harmed by Defendants' infringing activities and do not have an adequate remedy at law.

COUNT IV

Infringement of U.S. Patent No. 8,602,215 Under 35 U.S.C. §271(e)(2)

45. Plaintiffs repeat and reallege paragraphs 1 through 44 as if fully set forth herein.

46. By submitting ANDA No. 205895 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Alkem's Proposed Generic Product throughout the United States prior

to the expiration of the ’215 patent, Defendants committed an act of infringement of the ’215 patent under 35 U.S.C. §271(e)(2).

47. The commercial manufacture, use, offer for sale, sale, and/or importation of Alkem’s Proposed Generic Product, for which Alkem seeks approval in ANDA No. 205895, will infringe, induce infringement, and/or contributorily infringe one or more claims of the ’215 patent under 35 U.S.C. §§ 271(a), 271(b), and/or 271(c).

48. Plaintiffs will be irreparably harmed by Defendants’ infringing activities and do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for a judgment in their favor and against Defendants and respectfully request the following relief:

A. A judgment that under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed one or more claims of the ’493 patent by submitting ANDA No. 205895 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of Alkem’s Proposed Generic Product before the expiration of the ’493 patent;

B. A judgment that the manufacture, use, offer for sale, sale, and/or importation of Alkem’s Proposed Generic Product will infringe the ’493 patent;

C. A judgment declaring that the ’493 patent remains valid and enforceable;

D. A permanent injunction restraining and enjoining Defendants and their officers, agents, attorneys, and employees, and those acting in privity or concert therewith, from engaging in the commercial manufacture, use, offer for sale, sale, and/or importation of Alkem’s Proposed Generic Product until the expiration of the ’493 patent or any later date of exclusivity to which Plaintiffs are or become entitled;

E. An order that the effective date of any approval of Alkem's ANDA No. 205895 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date that is not earlier than the expiration of the '493 Patent or any later date of exclusivity to which Plaintiffs and/or this patent are or become entitled;

F. A judgment that under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed one or more claims of the '800 patent by submitting ANDA No. 205895 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of Alkem's Proposed Generic Product before the expiration of the '800 patent;

G. A judgment that the manufacture, use, offer for sale, sale, and/or importation of Alkem's Proposed Generic Product will infringe the '800 patent;

H. A judgment declaring that the '800 patent remains valid and enforceable;

I. A permanent injunction restraining and enjoining Defendants and their officers, agents, attorneys, and employees, and those acting in privity or concert therewith, from engaging in the commercial manufacture, use, offer for sale, sale, and/or importation of Alkem's Proposed Generic Product until the expiration of the '800 patent or any later date of exclusivity to which Plaintiffs are or become entitled;

J. An order that the effective date of any approval of Alkem's ANDA No. 205895 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date that is not earlier than the expiration of the '800 Patent or any later date of exclusivity to which Plaintiffs and/or this patent are or become entitled;

K. A judgment that under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed one or more claims of the '167 patent by submitting ANDA No. 205895 seeking FDA

approval for the commercial manufacture, use, offer for sale, sale, and/or importation of Alkem's Proposed Generic Product before the expiration of the '167 patent;

L. A judgment that the manufacture, use, offer for sale, sale, and/or importation of Alkem's Proposed Generic Product will infringe the '167 patent;

M. A judgment declaring that the '167 patent remains valid and enforceable;

N. A permanent injunction restraining and enjoining Defendants and their officers, agents, attorneys, and employees, and those acting in privity or concert therewith, from engaging in the commercial manufacture, use, offer for sale, sale, and/or importation of Alkem's Proposed Generic Product until the expiration of the '167 patent or any later date of exclusivity to which Plaintiffs are or become entitled;

O. An order that the effective date of any approval of Alkem's ANDA No. 205895 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date that is not earlier than the expiration of the '167 patent or any later date of exclusivity to which Plaintiffs and/or this patent are or become entitled;

P. A judgment that under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed one or more claims of the '215 patent by submitting ANDA No. 205895 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of Alkem's Proposed Generic Product before the expiration of the '215 patent;

Q. A judgment that the manufacture, use, offer for sale, sale, and/or importation of Alkem's Proposed Generic Product will infringe the '215 patent;

R. A judgment declaring that the '215 patent remains valid and enforceable;

S. A permanent injunction restraining and enjoining Defendants and their officers, agents, attorneys, and employees, and those acting in privity or concert therewith, from

engaging in the commercial manufacture, use, offer for sale, sale, and/or importation of Alkem's Proposed Generic Product until the expiration of the '215 patent or any later date of exclusivity to which Plaintiffs are or become entitled;

T. An order that the effective date of any approval of Alkem's ANDA No. 205895 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date that is not earlier than the expiration of the '215 patent or any later date of exclusivity to which Plaintiffs and/or this patent are or become entitled;

U. A determination that this case is "exceptional" under 35 U.S.C. § 285 and an award of attorneys' fees;

V. Costs and expenses in this action; and

W. Such other and further relief as the Court may deem just and proper.

MC DONNELL, BOEHNEN, HULBERT & BERGHOFF LLP

/s/ *Joshua R. Rich*
Joshua R. Rich (ID No. 6225923)
rich@mbhb.com
300 South Wacker Drive
Chicago, Illinois 60606
Tel: (312) 913-0001
Fax: (312) 913-0002

Attorneys for Plaintiffs Sanofi and Sanofi-Aventis U.S. LLC

OF COUNSEL:

William E. Solander
Daniel J. Minion
James R. Tyminski
FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, NY 10104
(212) 218-2100

March 19, 2014